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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,736	09/11/2000	James M. Zavislan	ML-0414DIV	3878

7590 11/19/2004

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EXAMINER	
SMITH, RUTH S	

ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 11/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/658,736	ZAVISLAN, JAMES M.	
	Examiner	Art Unit	
	Ruth S Smith	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,19-23,26-37 and 42-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *4,5 and 7* is/are allowed.

6)☒ Claim(s) *1-3,6,8,19,20,23,26-37 and 42-46* is/are rejected.

7)☒ Claim(s) *21 and 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/28/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 28, 2004 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,19,26,29,31-33,42-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Corcuff et al ("In Vivo Vision of the Human Skin with the Tandem Scanning Microscope"). The claims are directly readable on Corcuff et al which disclose the use of a confocal microscope to provide images representing optically formed sections. Corcuff et al disclose the microscope is modified to limit skin movements using a surface contact device. The device will inherently apply force and maintain an area of skin tissue under stress. The device will inherently apply force against at least the edges of the area of skin tissue being examined.

Claims 1,2,8,19,26-37,42-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Dhawan. The claims are directly readable on Dhawan which discloses a system for examining tissue by maintaining the tissue under stress and examining the tissue under stress with a confocal imaging camera. The means for maintaining the tissue under stress includes a platen 54 and suction means which applies a force against at least the edges of the area of skin tissue being imaged. The opening in the

platen 54 includes a material window as part of element 44. Placement of the platen with respect to the tissue to be imaged inherently includes the means for moving it into position as set forth in claim 2. The imaging head is capable of imaging a section of tissue from light returned from focused light under the surface of the tissue as seen in figure 3. The imaging means is capable of imaging sections through different planes given the volume of tissue imaged, therefore, the images appear to represent optically formed sections of the tissue.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2,6,8,27,28, 30,34-37, 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corcuff et al in view of Dhawan. Corcuff et al which disclose the use of a confocal microscope to provide images representing optically formed sections. Corcuff et al disclose the microscope is modified to limit skin movements using a surface contact device. The device will inherently apply force and maintain an area of skin tissue under stress. The device will inherently apply force against at least the edges of the area of skin tissue being examined. Corcuff et al fails to disclose that the means for maintaining the skin under stress comprises a platen. Dhawan discloses a system for examining tissue by maintaining the tissue under stress and examining the tissue under stress with a confocal imaging camera. The means for maintaining the tissue under stress includes a platen 54 and suction means which applies a force against at least the edges of the area of skin tissue being imaged. The opening in the platen 54 includes a material window as part of element 44. Placement of the platen with respect to the tissue to be imaged inherently includes the means for moving it into

position as set forth in claim 2. It would have been obvious to one skilled in the art to have modified Corcuff et al such that the means for maintaining the skin under stress is as taught by Dhawan. Such a modification involves the substitution of one known means for maintaining the skin under stress by application of force in the environment of an optical imaging camera for another. With respect to claim 6, Corcuff et al discloses a system for examining tissue by maintaining the tissue under stress and examining the tissue under stress with a confocal imaging camera. Dhawan discloses means for moving the imaging head with respect to the orifice in that the camera can be inserted into the device. In the absence of any showing of unexpected results, the means used to move the head in the modified Corcuff et al device would have been an obvious design choice to one skilled in the art.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Corcuff et al in view of Dhawan as applied to claim 2 above, and further in view of Jester et al, "In Vivo, Real-time Confocal Imaging". Jester et al disclose means for fixing the position of the imaging device with respect to an area of the patient before it is lowered into place on the patient. It would have been obvious to one skilled in the art to have further modified Corcuff et al such that it includes means for temporarily fixing the imaging with respect to the patient before it is moved into contact with the tissue. Such a modification allows for more precise positioning and handling of the device. Dhawan discloses means for moving the imaging head with respect to the orifice in that the camera can be inserted into the device. In the absence of any showing of unexpected results, the means used to move the head in the modified Corcuff et al device would have been an obvious design choice to one skilled in the art.

Claims 20,23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corcuff et al in view of Dhawan and Jester et al, "In Vivo, Real-time Confocal Imaging". Corcuff et al which disclose the use of a confocal microscope to provide images representing optically formed sections. Corcuff et al disclose the microscope is modified to limit skin movements using a surface contact device. The device will

inherently apply force and maintain an area of skin tissue under stress. The device will inherently apply force against at least the edges of the area of skin tissue being examined. Corcuff et al fails to disclose that the means for maintaining the skin under stress comprises a platen. Dhawan discloses a system for examining tissue by maintaining the tissue under stress and examining the tissue under stress with a confocal imaging camera. The means for maintaining the tissue under stress includes a platen 54 and suction means which applies a force against at least the edges of the area of skin tissue being imaged. The opening in the platen 54 includes a material window as part of element 44. Placement of the platen with respect to the tissue to be imaged inherently includes the means for moving it into position as set forth in claim 2. It would have been obvious to one skilled in the art to have modified Corcuff et al such that the means for maintaining the skin under stress is as taught by Dhawan. Such a modification involves the substitution of one known means for maintaining the skin under stress by application of force in the environment of an optical imaging camera for another. Jester et al disclose means for fixing the position of the imaging device with respect to an area of the patient before it is lowered into place on the patient. It would have been obvious to one skilled in the art to have further modified Corcuff et al such that it includes means for temporarily fixing the imaging with respect to the patient before it is moved into contact with the tissue. Such a modification allows for more precise positioning and handling of the device. Dhawan discloses means for moving the imaging head with respect to the orifice in that the camera can be inserted into the device. In the absence of any showing of unexpected results, the means used to move the head in the modified Corcuff et al device would have been an obvious design choice to one skilled in the art.

Claims 3,20,23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dhawan in view of Jester et al, "In Vivo, Real-time Confocal Imaging". Dhawan discloses a system for examining tissue by maintaining the tissue under stress and examining the tissue under stress with a confocal imaging camera. The means for

maintaining the tissue under stress includes a platen 54 and suction means which applies a force against at least the edges of the area of skin tissue being imaged. The opening in the platen 54 includes a material window as part of element 44. Jester et al disclose means for fixing the position of the imaging device with respect to an area of the patient before it is lowered into place on the patient. It would have been obvious to one skilled in the art to have modified Dhawan such that it includes means for temporarily fixing the imaging with respect to the patient before it is moved into contact with the tissue. Such a modification allows for more precise positioning and handling of the device. Dhawan discloses means for moving the imaging head with respect to the orifice in that the camera can be inserted into the device. In the absence of any showing of unexpected results, the means used to move the head would have been an obvious design choice to one skilled in the art.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dhawan. Dhawan discloses a system for examining tissue by maintaining the tissue under stress and examining the tissue under stress with a confocal imaging camera. The means for maintaining the tissue under stress includes a platen 54 and suction means which applies a force against at least the edges of the area of skin tissue being imaged. The opening in the platen 54 includes a material window as part of element 44. Dhawan discloses means for moving the imaging head with respect to the orifice in that the camera can be inserted into the device. In the absence of any showing of unexpected results, the means used to move the head would have been an obvious design choice to one skilled in the art.

Allowable Subject Matter

Claims 4,5,7 are allowable over the prior art of record.

Claims 21-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claims 1-3,6,8,20,23,26-37,42-46 have been considered but are moot in view of the new ground(s) of rejection. With respect to the Dhawan reference, it appears that the device is capable of providing images that represent optically formed sections of tissue. With respect to claim 26, the reference previously relied upon would have been capable of functioning as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S Smith whose telephone number is (571) 272-4745. The examiner can normally be reached on M-F 7:30 AM- 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth S Smith
Primary Examiner
Art Unit 3737

RSS